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Patent

Attorney's Docket No. 032491-044 (001/001)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Luo, et al.

Application No.: 09/456,110

Filed: December 7, 1999

For: METHOD AND SYSTEM FOR TREATING
STROKE USING HYPERTHERMIA

) BOX AF

) Group Art Unit: 3763

) Examiner: Hayes, Michael J.

) Appeal No. 5994

)

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BRIEF FOR APPELLANT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This appeal is from the decision of the Primary Examiner dated August 1, 2002, twice rejecting Claims 1-3, which are reproduced as an Appendix to this brief.

A check covering the [X] \$160.00 (2402) [] \$320.00 (1402) Government fee and two extra copies of this brief are being filed herewith.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in triplicate.

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I. Real Party in Interest

The present application is assigned to Alsius Corporation.

II. Related Appeals and Interferences

The undersigned legal representative, or assignee does not know of any other appeal or interferences which will affect or be directly affected by or have bearing on the Board's decision in the pending appeal.

III. Status of Claims

Claims 1-44 were originally presented for examination. Claims 5-44 were canceled in a Response dated June 26, 2001, to the Restriction Requirement mailed May 31, 2001. Claims 45-47 were added in a Response dated December 20, 2001. Claims 4 and 45-47 were canceled in a Response dated July 18, 2002. Remaining Claims 1-3 are herein under appeal.

IV. Status of Amendments

There are no outstanding amendments after final rejection. All amendments have been entered.

V. Summary of the Invention

The invention is directed to the treatment of stroke, and more particularly, to a method for lowering body temperature in order to mitigate damage resulting from stroke.

Clinically, stroke is defined as "the sudden diminution or loss of consciousness, sensation, and voluntary motion caused by rupture or obstruction (as by a clot) of an artery of the brain."¹ The effects of stroke—that is, initial stroke severity, infarct size, mortality and outcome in survivors—are functions of body temperature. Lowered body temperature during and after a stroke mitigate these effects and reduce patient mortality. A stroke

¹Merriam Webster's Collegiate Dictionary, tenth edition, 1966.

patient's condition may be significantly improved if the patient's body temperature is mildly or moderately cooled to about 32°C - 36°C (normal body temperature is 37°C) relatively quickly for a short period—for example, 1 - 2 hours.

In view of the above, the present invention proposes the use of an indwelling cooling catheter designed to lower the patient's body temperature. Specifically, a heat exchange catheter (18, 28) in which a cooling fluid is circulated is introduced into the patient's central venous system. The cooled heat exchange catheter draws heat from blood flowing past the catheter to the rest of the body.

The central venous system provides direct and immediate access to a large volume of blood flow. The core temperature of the body as a whole is lowered, in a systemic approach, rather than a localized approach which targets solely the brain. Access to the central venous system results in very efficient and rapid cooling of the body, including, importantly, the stroke-impacted brain. Systemic cooling is less complex than localized cooling of the brain, and can therefore be performed rapidly and efficiently. Accordingly, remedial measures can be quickly taken following a stroke, thereby containing the resultant damage. Moreover the central venous system presents a convenient site for medical personnel involved in the treatment, as it is often already accessed for use in other procedures such as drug administration, thus obviating the need for further incisions and intubation.

VI. The Issues

The sole issue for consideration is whether the rejection of Claims 1-3 under 35 U.S.C. § 103(a) based on a combination of Dato (U.S. Pat. no. 3,425,419; hereinafter, "Dato") or Ginsburg (U.S. Pat. no. 5,486,208; hereinafter, "Ginsburg") in view Dobak, III et al. (U.S. Pat. no. 6,254,626; hereinafter, "Dobak") and Fox (U.S. Pat. no. 6,090,132; hereinafter, "Fox") is proper.

VII. Grouping of Claims

Claims 1-3 stand or fall together.

VIII. Argument

Appellants respectfully maintain that neither Dato nor Ginsburg is properly combinable with Dobak and Fox, and that such combinations in any case would neither teach nor suggest the presently claimed invention.

Dato discloses lowering patient body temperature using an indwelling catheter (10) in which cooling fluid is circulated. Dato primarily seeks to induce "moderate hypothermia as an aid to surgery on the heart."² The surgery contemplated by Dato is specific in nature, and involves corrections to be made "in cases of pulmonary infundibular or valvular stenosis, in cases of arterial-septal defects, and in cases of rapid operations on the mitral valve."³ (Emphasis added). The rapidity requirement is notable because these corrections occur in a bloodless heart,⁴ and therefore involve severe constraints in time, and introduces myriad complications. Specifically, according to Dato, "the circulatory arrest can not exceed eight to ten minutes and the surgeon must operate during this time."⁵

There is no mention in Dato of treatment of stroke, or of the benefits of lowered body temperature in mitigating the effects of stroke. Stroke, it will be appreciated, is a brain condition, whereas the focus in Dato is primarily on conditions of the heart, and the procedures and constraints of Dato are specific to the heart and its unique physiological requirements.

Dobak is directed to cooling of organs of a body by removing heat from their feeding arteries.⁶ Dobak treats brain conditions in this manner, and directs heat transfer element 14 into one or both the common carotid artery and the internal carotid artery,

²Dato, col. 1, ll. 25 - 26.

³*Id.*, col. 1, ll. 32 - 35.

⁴*Id.*, col. 1, ll. 32 - 33.

⁵*Id.*, col. 4, ll. 27 - 29.

⁶Dobak, col. 5, ll. 26 - 29.

considered the feeding arteries of the brain.⁷ Heat transfer element 14 operates to remove heat from the blood flowing to the brain, cooling the brain in this deliberately localized manner.

There is no motivation for combining the teachings of Dato with those of Dobak. Dato does not mention or address treatment of stroke, and does not recognize the benefits of lowered body temperature in specifically mitigating the effects of stroke. Dobak, by comparison, takes a localized approach to lowering body temperature, and as discussed below, argues forcefully against the systemic approach of Dato. Appellants respectfully maintain therefore that the combination of Dato and Dobak is improper. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination."⁸ (Emphasis original).

Rather than express the desirability for the combination, Dobak takes great pains to distinguish its teachings from those of Dato. According to Dobak, the cooling technique of Dato is unsatisfactory because it is systemic, rather than localized, in nature. Dobak states that ". . . the use of total body hypothermia risks certain deleterious systemic vascular effects . . . [and] . . . is difficult to administer."⁹ Further, Dobak specifically rejects the teachings of Dato, stating that ". . . [The] use of the Dato device implicates the negative effects of total body hypothermia. . ."¹⁰ Dobak thus effectively teaches away from a combination with Dato. "It is improper to combine references where the references teach away from their combination."¹¹

The combination of Dato with Fox is also improper. Fox does not teach or suggest

⁷*Id.*, col. 5, ll. 55 - 61.

⁸MPEP § 2143.01, citing *In re Mills*, 16 USPQ 2d 1430 (Fed. Cir 1990).

⁹*Id.*, col. 1, ll. 51 - 59.

¹⁰*Id.*, col. 2, ll. 7 - 8.

¹¹MPEP § 2145(X)(D)(2), citing *In re Grasselli*, 218 USPQ 769, 779 (Fed. Cir 1983).

the use of any type of vascular cooling catheter to lower body temperature. Rather, in Fox, the approach is to actually heat the hypothalamus gland in the brain, to thereby "trick" this body temperature-controlling organ into believing that the body is overheating, and into taking the desired corrective cooling measures. Access to the hypothalamus is gained through the surrounding brain tissue, or through the nasal passage or sinus, into which is introduced a gas-emitting catheter (7), inserted in the patient's nostril for instance. There is no teaching or suggestion of "advancing a heat exchange catheter . . . into a central venous vein" of the patient, as set forth in Claim 1.

The reverse "cooling" approach disclosed in Fox is rationalized as a way of overcoming the body's natural resistance to lowered body temperature, which resistance has allegedly confounded conventional, direct cooling approaches. There is no motivation to combine the reverse cooling teachings of Fox with the direct cooling teachings of Dato. The objective in Fox is avoid having to directly cool the body and contend with its natural resistance to this cooling. Fox thus teaches away from such a combination and from the invention as claimed.

Ginsburg discloses using a catheter 20 (FIG. 6) to lower the temperature of a patient and "induce an artificial condition of hypothermia when desired, e.g., to temporarily reduce a patient's need for oxygen."¹² Ginsburg does not specifically address treatment of stroke. Catheter 20 is inserted into the femoral vein or artery or the jugular vein.

Like Dato, Ginsburg performs systemic cooling of body temperature, and therefore, like Dato, Ginsburg's teachings can not be properly combined with those of Dobak. Specifically, Dobak discusses at length the inadequacies of taking a systemic approach to cooling body temperature, expressly rejecting Dato, and implicitly rejecting the similar approach of Ginsburg. Thus, the reasoning above that Dobak teaches away from a combination with Dato, applies to Ginsburg as well, and militates against combining Dobak with Ginsburg.

Similarly, the combination of Ginsberg and Fox is untenable, with Ginsburg

¹²Ginsburg, col. 4, ll. 14-15.

disclosing lowering body temperature using a catheter to cool the body while Fox discloses reverse "cooling" through heating the hypothalmus. Ginsburg does not teach or suggest treatment of stroke, and Fox seeks to circumvent the body's resistance to cooling by avoiding externally imposed cooling, and instead "tricking" the hypothalmus into utilizing the body's own cooling mechanisms. Thus, there is no motivation to combine the teachings of Ginsburg and Fox.

IX. Conclusion

Appellant respectfully maintains that for the above reasons, the rejection under 35 U.S.C. § 103(a) of Claims 1-3 based on the combination of Dato or Ginsburg in view Dobak and Fox is improper.

Early and favorable consideration is respectfully solicited.

Respectfully submitted,

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APPENDIX

TheAppealed Claims

1. A method for treating stroke patient, comprising the acts of:
 - identifying a stroke patient for treatment;
 - advancing a heat exchange catheter into said patient wherein said heat exchange catheter is advanced into a central venous vein of said patient; and
 - inducing hypothermia using said heat exchange catheter.
2. The method of Claim 1, further comprising the act of monitoring said patient's blood pressure level.
3. The method of Claim 2, further comprising the act of maintaining said patient's blood pressure at a desired blood pressure level.



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